LABTrack™ - Introducing a Legal Electronic Lab Notebook.

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“Your observations are to be taken with great pains and accuracy, to be entered distinctly and intelligibly for others as well as yourself.”

- President Thomas Jefferson’s written instructions to Meriwether Lewis, 1803
Outline

• Legal foundation for paper notebooks.
• Requirements for use.
• Benefits of an Electronic Lab Notebook.
• Concepts of an Electronic Lab Notebook.
• Legal Aspects of “Going Electronic”.

Legal Foundation of Using Paper

• Non-repudiation characteristics.
• Courts consider notebooks to be standard business records - fall under “hearsay” exception.
• US PTO issues patents based upon date of invention (not date of application).
Requirements of a Paper Laboratory Notebook

• Longevity - At least 25-50 years.
• Archival quality paper, ink and adhesive.
• Bound and serialized pages to support chronology.
• GLP for Non-Clinical Lab Studies (21 CFR Part 58)
Typical Rules for Using a Paper Lab Notebook

- Entries in permanent ink written immediately after work is performed.
- All entries must be signed and dated.
- Unwanted data is lined-out, initialed, dated and the reason for change explained in writing.
- Writing must be legible, grammatical & complete.
- Entries must be read, signed & dated by witness other than co-inventor.
- Notebooks must be stored safely when not in use.
Why Consider an ELN?

- Legibility.
- Searching.
- Reporting.
- Distribution & Communication.
- Backup and Archival.
- Enforcement of Legal and Corporate Standards.
LABTrack Milestones

• Development started April, 1997.
• First commercial version shipped Jan ‘98 - included Electronic Signature.
• To date ~ 200 Companies, ~ 600 users.
• Introduced LABSafe™ Legal Compliance - March 2001.
LABTrack Objectives

• Evolve LIMS into a true replacement for laboratory notebooks.
• Provide comparable functionally - from the perspectives of the authors, witnesses and readers.
• Legally Acceptable in US Court of Law, before US PTO, and to regulatory agencies of Federal and State Governments.
LABTrack Design Components

• Microsoft Windows® application.
• Notebook Module - Scientific Word Processor - supports Object Linking & Embedding (OLE).
• LIMS-like Database and Forms.
• LABSafe™ - Addresses legal requirements for electronic record keeping.
• LABWise™ - Lab notebook rules set.
LABTrack Notebook Module

- Pages saved as records in the underlying database.
- Allows embedding of objects (photos, files, spreadsheets, spectra, chromatograms, etc.)
- Automatically searches for and stores data about projects, samples, results and materials.
- Includes Witnessing / Approval function.
LABTrack Notebook Module

- Notarized page icon
- Lined-out text with who, when & why.
- Embedded spreadsheet
- User created bookmarks
- OLE Application Toolbar
- User defined special character keypad

**What Kind of Objects Can You Embed on a Page?**

You can embed objects from all kinds of applications on a notebook page. The list is limited only by what applications are installed on your computer. The next few pages show some examples.

Written by Richard on 7/11/00 2:48:47 PM
Approved by John on 7/12/00 3:20:18 AM

**Microsoft Excel:**

While it is easy to embed custom Excel spreadsheets, LABTrack also includes Wizards for creating and embedding spreadsheets for unique chemistry applications including a Formulation Wizard and a Multiple Results Entry Wizard. An example of a formulation table is shown here:

<table>
<thead>
<tr>
<th>Component</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - Component1</td>
<td>45</td>
<td>15</td>
<td>45</td>
<td>15</td>
</tr>
<tr>
<td>2 - Component2</td>
<td>35</td>
<td>15</td>
<td>35</td>
<td>15</td>
</tr>
<tr>
<td>3 - Component3</td>
<td>25</td>
<td>15</td>
<td>25</td>
<td>15</td>
</tr>
<tr>
<td>4 - Component4</td>
<td>25</td>
<td>15</td>
<td>25</td>
<td>15</td>
</tr>
</tbody>
</table>

**Microsoft Chart:**

Most people don’t realize Windows comes with an easy to use graphing applet called chart. Of course, if you want you can embed more sophisticated charts using specialized charting.
LABSafe™ - Electronic Signature

- Controlled User Names / Passwords.
- Biometric devices such as Finger Print Readers, Face Pattern Recognition, etc.
LABSafe™
Digital Notary Services

• Provided by Surety Technology, Inc. (www.surety.com).
• Provides legal proof that the page has not been modified.
• Uses either on-site notarization servers or Surety’s servers on the Internet.
• Independent, Impartial 3rd Party.
• Fully Automatic - Collusion is not possible.
Digital Notarization

• One-Way Hash Fingerprint is Sent to Notarization Server.
• Probability of two records having same hash: 1 : 1 x 10^{87}
• Pages Cannot Be Recreated from Hash.
Digital Notarization

LABTrack

- D/T Stamp and ID Sent Back & Stored.
- Fingerprint Stored in Universal Registry.
- SuperHashes are Published in NY Times placing them in the public domain.

Notarization Server

Date/Time Stamp & ID

Universal Registry

5hGe89Au4L1... Kj19oHflk37j...
Is “Going Electronic” Legal?

- FDA Rules
- U.S. PTO Position
- Federal Law
- Court Precedents
U.S. FDA Rules

- Electronic Signature - 21 CFR Part 11
- CDER & CBER Standards for Electronic Submissions
  1. Files in PDF format - Portable Document Format (Adobe Systems, Inc.)
  2. Datasets in SAS XPORT transport format (SAS Institute)
Where Does the PTO Stand?

- Admissible as evidence before the Board of Patent Appeals

  “Pursuant to 37 CFR Sec 1.671, electronic records are admissible as evidence in interferences before the Board of Patent Appeals and Interferences to the same extent that electronic records are admissible under the Federal Rules of Evidence.”²

Federal Rules of Evidence (FRE) Allow Electronic Records if:

• They can be **Authenticated** - Authentication “is satisfied by evidence sufficient to support a finding that the matter in question is what its proponent claims” FRE 901(a)

• They are **Admissible** under specific rules - The most common bar to admissibility is hearsay.
  “It is clear that the content of a properly authenticated notebook record, adopted as true by its author, is not hearsay.” ³
What if the author is not available ...

- It is still **Admissible** -

  “...a notebook record, made during the ordinary course of business, is admissible under the business record exception to the hearsay rule provided in Rule 803(6).”
Does it Standup in Court?

• U.S. v. Glasser and other cases
  “Importantly, Glasser and other cases to date have been clear that electronic evidence is not deemed inherently less reliable or trustworthy than paper records.”

• 3M v. The Ansol Co.
  The court found specifically a lab report and lab notebook fall within the business record exception of the hearsay rule. They were found to be products of standard business procedures.
• **In U.S. v. Briscoe**

The 7th U.S. Circuit Court of Appeals allowed the admission of computer records...where the party presenting the records “provides sufficient facts to warrant a finding that the records are trustworthy and the opposing party is afforded an opportunity to inquire into the accuracy thereof and how the records were maintained and produced” ³
LABSsafe™ and FRE

- DNS provides the **WHAT** and **WHEN** for needed record Authentication
- Electronic Signature - provides the **WHO**
Longevity Considerations

• Life Expectancy of CD-R media 70 - 200 years \(^6\).
• Occasional migration to newer media types (every 5 ~ 10 years).
• Routine transfer to alternative data formats (example: PDF).
Conclusion

- Electronic Lab Notebooks are a Reality.
- Offer Enhanced Capabilities over Paper.
- Are Legally Acceptable as Replacement for Paper Notebooks.
- Do Not Require Special Expertise to Implement, Use Safely and Efficiently.
References


4 *Guidance for Industry, Providing Regulatory Submissions in Electronic Format - General Considerations* Food and Drug Administration CDER & CBER, January 1999


6 Life expectancy studies done respectively by TDK and KODAK www.cd-info.com/cdic/technology/cd-r/media, The CD Info Company